Public Meeting on Ethylene Oxide

May 29, 2019, 6:00 PM – 10:00 PM

Chicago Marriott Southwest at Burr Ridge - Ballroom

1200 Burr Ridge Parkway, Burr Ridge, IL 60527

Remote participants joined by visiting the Burr Ridge Facebook page for a livestream of the meeting.

MEETING START

Facilitators, Doug Sarno, of The Participation Company, and Kristi Celico, of Rocky Mountain Collaborative Solutions, called the meeting to order and reviewed the approach and meeting agenda. The meeting items included:

- Four reports were created by different state and federal agencies to assess the impacts of the Sterigenics site in Willowbrook.
- Information about the EPA National Rule For Commercial Sterilizers and next steps.
- Next steps for Ethtlene Oxide (EtO) sites in Illinois.
- Community members were selected to ask questions on behalf of the community from those gathered by the EPA over the past weeks in regard to the Sterigencs site.
- EPA will have a follow on Webinar that will allow for additional questions to be answered and provide additional information, as it becomes available.
- For additional comments or questions, email: eto@epa.gov

WELCOME

Agency and Local Officials discussed their goals and expectations for the meeting.

- USEPA Region 5 Administrator - Cathy Stepp
    - Agency scientists and engineers have done a lot of work to understand EtO, and the effects it has on the environment.
- USEPA Assistant Administrator for the Office of Air and Radiation - Bill Wehrum
    - USEPA is taking the concerns around EtO very seriously, and he appreciates the community involvement. He is attending the meeting to present on the regulatory work the USEPA is doing for EtO.
- Burr Ridge - Mayor Gary Grasso
    - Mayor Grasso stated that it is his job, the job of the community board, and the government to protect public health, and he is committed to that.
    - Bill SB1852 was passed in the Illinois General Assembly, and Illinois will soon have the toughest EtO legislation in the nation.
- Willowbrook - Mayor Frank Trilla
    - On August 22, 2018, the USEPA reclassified EtO from “possibly carcinogenic” to “carcinogenic,” but provided no additional information and what steps would be taken because of this classification. Willowbrook has worked with local and state leaders as well as with the EPA to conduct indoor and outdoor testing over a 30-day period. This produced data that was needed so he and other local leaders can continue to work toward a solution and protect the community.
- Stop Sterigenics & Citizens for Clean Air - Margaret Donnell & Neringa Zymancius
    - Stop Sterigenics and Citizens for Clean Air did not have an opportunity to review the risk assessment before it was release on the day of the meeting. They expressed disappointment in the transparency around the release of the risk assessment. The reiterated that the Sterigenics facility is not shut down and they are working to have it shut down, and also working to ensure that Sterigenics does not open a facility in another community.
- Illinois Department of Public Health - Acting Director Dr. Ngozi Ezike

    - The Illinois Department of Public Health conducted a cancer study. Cancer studies are data-based and created using statistical analysis. Their study did find that some cancers were elevated. It is difficult for any single study to prove that a specific thing causes a specific cancer. The Illinois Department of Public Health is committed to further study on this issue and sharing that information in a timely manner.
- Illinois EPA - Acting Director John Kim
    - The IEPA wants as much information as possible extended to the public, and this is the most important issue in Dr. Kim's office currently. The IEPA is working to use every tool available to address the situation and will continue to work closely with their partners and legislators on this issue. Due to the ongoing nature of the legislation, there are some answers that cannot be given during the meeting.

PRESENTATIONS ON CURRENT STUDIES AND REPORTS

Agency staff provided updates and results from recent health and environmental studies on the Willowbrook Sterigenics facility.

- Overview of Current Information—Mike Koerber, USEPA
    - Mr. Koerber thanked the Villages that attended the meeting as well as the different agencies. He then explained the differences between the state and federal EPA. The IEPA issues air permits and has different roles and responsibilities than the federal EPA, however, both agencies are responsible for enforcing the Clean Air Act.
    - The USEPA has conducted the risk assessment and is releasing the information from that study. The risk assessment and the other reports that are discussed during this meeting all share important information that help characterize EtO. The development of the risk assessment and the other studies take time to ensure the accuracy of the information. The Willowbrook meeting provides an opportunity to discuss what has been done and what other actions still need to take place.
    - Based on the USEPA's testing of the Sterigenics facility, the emission levels require regulatory action. The USEPA will work with the state of Illinois to control the emissions.
    - The USEPA collected samples over a four-and-a-half month period, most of the samples were collected before the seal order and some were after, so USEPA has data for both. Based on the data collected, USEPA believes that the risk associated with the current conditions and needs to be regulated.
    - USEPA is working on tailored solutions for individual areas because the national rule is for the whole nation, and would underserve the specific areas more effected. Additionally, USEPA wants to improve national inventories for EtO.
- IEPA Well Water Sampling – Brad Frost, IEPA
    - The IEPA conducted private well water samples within one mile of the Sterigenics facility. The IEPA conducted monitoring on all private wells to which they were granted access. The result off all tests came back as non-amounts.
- EPA Risk Assessment – Kelly Rimer, USEPA
    - Ms. Rimer presented information from the National Air Toxics Assessment. The assessment found that the pre-seal levels do require regulatory action. The USEPA is required by the Clean Air Act to regulate and determine how much a facility can release into the air.
    - The study area covered several villages around the Willowbrook facility. The assessment looked at the pre-seal order data and after the seal order. The risk assessment looks at potential risks for the future, but also has to consider other factors like leaks from windows and doors, and ensure control measures are operating properly. Looked at potential risks for future and what that might look like if there are more controls put on the facility.
    - The assessment looks at facilities all over the country, as is required by the national rule.

    - The risk assessment looked at two different types of exposures: residents, which assumes 24/7 exposure over 70 years breathing this air; and those who work close to the facility and do not have constant exposure.
    - This assessment focuses on EtO from Sterigencs. It does not include other pollutants and EtO from other sources.
    - The study can provide general information on the risks. There are a number of other risks that can cause cancer and this study does not consider other possible individual risks.
    - This study is more likely to overestimate the risks than underestimate. Ex: most people do not live somewhere for 70 years, but that is the time that is considered for this study.
    - Maximum risk is 1,000 in a million and that is 1/3 mile from the facility. The highest risk is 1,000 in a million to 100 in a million and less further out from the facility.
    - The risk is less than 10 in a million in the illustrative future case.
    - The risk to workers (those who do not have constant exposure) within a quarter of the mile also goes down from 1,000 in a million.
    - The Risk Report will be posted when it is complete.
- Update on ATSDR follow up Health Consultation – Mark Johnson and Michelle Colledge, ATSDR
    - Agency for Toxic Substances and Disease Registry (ATSDR) is a federal public health agency that conducted a health consultation for the area surrounding the Sterigenics facility.
    - The final conclusions and recommendations have not yet been released.
    - EPA Region 5 provided some data for the assessment for EtO facilities in the US and asked ATSDR for technical guidance to look at health impacts on the public near these facilities. ATSDR received a few days worth of data, and assessed that the measured levels indicated that there are potential cancer risks.
    - ATSDR recommended that EPA conduct a longer-term exposure scenario. ATSDR is conducting a follow-up study to look at current exposure and the concentration at different distances.
    - ATSDR is evaluating a number of data sets as part of their study including: data from the Chicago area and other states; historic data; other sterilizers in Michigan and Colorado; variations in concentration over space and time and weather conditions; and risks associated with these toxins.
    - ATSDR is trying to determine a baseline and what the contribution is from Sterigenics.
    - The preliminary summary of EPA's data shows that Sterigenics is operating is between two and ten times higher with different risks within different parts if the community. The data shows a concentration over time for levels of EtO. All the EtO contaminants are coming from Sterigenics, and the concentration of EtO stabilizes after the plant was capped.
    - The assessment looked at the concentrations around the schools in the area and the trends are the same as other air monitoring sites in the area.
    - The air monitoring sites show the concentration and the direction that the contaminant is coming from. ATSDR is looking at mobile sources, but in this range, the contamination is clearly linked to the facility, not other mobile sources.
    - ATSDR is trying to identify a baseline risk across the US. The data they have collected from New England, Colorado, Michigan, and Chicago shows there is a baseline risk for EtO.
    - ATSDR is hoping to finish the study assessment for this soon and have it published. ATSDR will than plan for a forum to discuss the final findings that will allow for questions.
- IDPH Cancer Study— Kyle Garner and Dr. Tiefu Shen, IDPH
    - The IDPH Cancer Study used the 2010 census tracts. These tracts were selected based on their proximity to the plant and information from EPA's data. The second study area was based on census tracts and zip codes. IDPH used both the census tracts and zip codes when comparing the data.
    - 1995 to 2015 was the most recent information IDPH had available on cancers in Illinios.
    - Blood cancers and female breast cancer instances were assessed in this study because they are associated with EtO. The study found that the breast cancer levels are not higher in the study area than in the surrounding county. The study also looked at trends in EtO-related sites.

- There were no other sites that displayed clear trends over time.
- There are no trends across all study areas.
- State and County data were used as a reference for the EtO-related areas.
- These results should be used with caution because this is the first time a population study has been used for this study.
- IDPH is unable to test individuals to see if they have been exposed to EtO.
- IDPH does not have additional data on other risk factors for cancer. Cancer is a complex disease and controls were added when conducting the study to account for the complexities.

STAKEHOLDER Q&A PANEL ON THE STUDIES AND REPORTS

The stakeholder panel members asked questions related to the current reports that are most important to the community, including any questions gathered at the Open House. The panelists were:

- Richard Morton - EtO Medical Monitoring
- Greg Hart - DuPage County Board Member
- Urszula Tanouye - Stop Sterigenics
- Dr. Susan Buchanan - University of Illinois-Chicago
    - Describe the difference between cancer "risk" and cancer "incidence." "Risk" is an individual's chance of getting cancer. "Incidence" is the number of cancer cases. Risk tells us the possibility of something that may happen in the future. Incidents are the reality of the risk.
    - ATSDR and EPA both conducted assessments, what is the difference? ATSDR's assessment is based on risk measurements at the risks associated with based on the current EtO exposure levels. EPA's assessment is based on modeling, which projects what future exposure could be and assesses future risk.
    - How does the risk assessment account for half-life for EtO? EtO is stable so the study did not account for half-life.
    - IDPH's census tract data did assess the residents in the area, and how far the risk extends from the facility. The census tract is nine miles from the facility. This tract was selected to provide data to the community as quickly as possible.
    - Individuals have moved out of the area and they are not being considered as part of this assessment, there needs to be long-term follow-up for those exposed. There are comparative populations in the study and other counties in Illinois, including Lake County. There is another facility in Lake County, so the Cancer Study needs to be reassessed with a different baseline because there is also exposure to EtO in Lake County.
    - Is the risk assessment adjusted for age and how would that change?
        - EtO is more potent for children and that is included in the assessment.
        - The Clean Air Act requires assessment for 70 years, which is a lifetime risk, as part of the regulatory program. ATSDR's assessment looked at half lifetime (33 years).
    - What medical signs should youth look for to determine if there is an issue from exposure? Symptoms are often vague, like fatigue. Residents are encouraged to do a blood count on an annual basis or when symptoms present themselves.
    - Are these emissions higher or lower when compared to other time periods and what is the risk? There is not sufficient historical data to determine what the risks are or if the risk has changed.
    - How does EtO move through the air and what weather conditions effect the movement? Moves with the wind; precipitation does not play a role, as rain does not wash it out.
    - Does the EPA assessment look at travel exposure? No, this is rolled into the constant exposure and designed to be protective of the whole population. When looking at the information in the EPA and ATSDR studies, assume a continuous exposure.
    - The EPA's focus has been outdoor data and not indoor data.
    - There was not a lot of information about this chemical prior to this testing, but most of what was measured could be used.

- When Sterigenics did their testing, it was one pipe from each facility and looked at the emission measurements around the facility. Sterigenics self-reported that there were over 200,000 pounds going into the air, and the assessments are based on their self-reporting for 2,000 pounds for year.
- The risk assessment focuses on the risk for the highest exposure.
- There is dialog between Sterigenics and EPA because EtO is going to be regulated and there needs to be a significant amount of discussion and it is EPA's responsibility to try and ensure cooperation with those who are being regulated.

NEXT STEPS

Bill Wehrum from the USEPA, and John Kim from the Illinois EPA discussed what actions their respective agencies have taken in regard to EtO and the Sterigenics facility in Willowbrook, IL.

- EPA: EPA National Rule For Commercial Sterilizers - Bill Wehrum
  - Current data on EtO is out-of-date and this does not affect most of the country. Normally, EPA would regulate for this, but the regulatory processes take years. EPA determined that they do not want to take months or years to regulate EtO, and instead would go into communities with high levels of EtO occurrence and conduct site-specific assessments and work with the local governments for developing a remedy.
  - EPA has had regulations in place for commercial sterilizers, and the regulations were last updated in 2001. In April 2006, a risk assessment was conducted to review the rule and see if it is still accurate. EPA is in the process of developing a revised rule and that will released soon, and the public will be able to contribute to the rule.
- IEPA: Next Steps on Sterigenics facility in Willowbrook, discussion of IEPA Litigation - John Kim
  - IEPA currently is working on litigation, because that is still in process; there is some information that cannot be shared at the meeting.
    - USEPA is in process of going forward with new proposal that would build upon existing requirements for EtO, and state would track and provide comments as needed.
    - IEPA is working to create a new section in the Environmental Protection Act and allows for investigation and action, prosecutions, and litigation at the state level. This litigation focuses on chemical sterilizing sources, and these facilities will not be able to operate unless they have obtained controls. Part of the requirement for these facilities will be that they create an inward draw so that there are no leaks. The facilities would be required to have an initial emissions test of the surrounding areas, and plants must be reviewed and approved, with annual testing. There also has to be continuous collection of emissions information and monitoring. There is a specific note in the litigation about a seal order with an additional certification for this source that this is the only method that can be used for medical sterilization. The litigation further discusses intellectual property as it pertains to the development of other sterilization methods. New facilities must have setbacks from the public. Deviations from the litigation must be reported and will be made public. IEPA will conduct statewide EtO monitoring and will submit rules for air testing that expand beyond the legislation.

STAKEHOLDER Q&A PANEL ON NEXT STEPS

Stakeholder panelists asked questions related to next steps that are most important to the community, including questions gathered at the Open House.

- Margaret Donnell - Citizens for Clean Air, NFP
- Srikant Rao - Stop Sterigenics
- Neringa Zymancius - Stop Sterigenics
- Julie Renehan - DuPage County Board Member
- Questions
  - What is the responsibility of the EPA and IEPA on how to monitor EtO moving forward? For national regulations, USEPA will look at risks and how to assess these risks for creating regulations. USEPA is responsible for regulating for general levels of risk. All facilities have

some kind of emission and EPA has to determine what the appropriate level of risk is. States are responsible for enforcing regulations from the state or federal level. States determine what permitting and action takes place when there is non-compliance. States cannot be less stringent in their regulations or the enforcement of regulations than the federal government. The state of Illinois is currently working to have more stringent litigation passed with 99.9% controlled efficiency for facilities, while the federal level is 99.5%.

- A "highly controlled facility" is a facility with the least amount of emissions. This facility would use state-of-the-art technology to reduce emissions. There are many ways that facilities release emissions, with point source being the largest outlet for emissions. Pint source emissions are emissions from a stack. The other emissions sites, like leaks, need to be assessed and controlled at facilities.
- Cost has not been raised as an issue or consideration with the new litigation.
- Is Sterigenics required to follow NESHAP or Title V permitting? IEPA is using the permitting as the enforcement needs. Title V is not to impose emissions controls on a facility.
- Sterigenics does not qualify as a major source under Title V, so they are not required to do continuous monitoring.
- The local emissions requirements needs to be complied with the requirements regulated by the state.
- A request was made that regulations be imposed based on the type of chemicals released, not based on what a facility says its processes are or how the facility functions.
- EPA is still monitoring EtO to see if there are other sources for EtO. EPA is going to look at other monitoring area to see if there are other sources besides the medical sterilization facilities.
- In 2016, EPA updated its standards when additional information about EtO was found that it is a toxic emission. For risks that are over 1 in a million, EPA is required to take action. USEPA cannot shut down Sterigenics, USEPA can only reduce risk, but cannot eliminate risk. USEPA will continue monitoring residual risk and to continue monitoring.
- IEPA will propose rules for regulation, but there is a huge effort that has to be undertaken for statewide regulation.